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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, and the NATIONAL COMMUNITY PHARMACISTS ASSOCIATION,

Plaintiffs,

v.

ARNOLD SCHWARZENEGGER, not individually, but solely in his official capacity as Governor of the State of California, KIM BELSHE, not individually, but solely in her official capacity as Secretary of the California Health and Human Services Agency, DAVID MAXWELL-JOLLY, not individually, but solely in his official capacity as Director of the California Department of Health Care Services, and THE CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES,

Defendants.

Case No.: CV09-07097 CAS (MANx)

PLAINTIFFS' RESPONSE TO DEPARTMENT OF JUSTICE STATEMENT OF INTEREST

Date: December 7, 2009
Time: 10:00 a.m.
Courtroom: 5

Trial Date: TBD
Action Filed: September 30, 2009

Honorable Christina A. Snyder

I. INTRODUCTION

The Department of Justice ("DOJ") brief addresses *one* issue: whether "the reduction in AWPs caused by the *First Databank* settlement requires Medi-Cal to submit a state plan amendment for approval by the Secretary through the … [CMS]." [DOJ Brief, p. 3:9-13.] What is significant about the belatedly-filed[1] Statement of Interest brief is that the DOJ *does not* contend that California complied with Section 1920(a)(30)(A) of the Social Security Act. As this compliance is central to Plaintiffs' argument for the issuance of the preliminary injunction, the Statement of Interest brief is superfluous.

Even more significant is the DOJ's express agreement with the Plaintiffs as to the requirement of Section 1920(a)(30)(A). However, the DOJ fails to analyze whether the changes in the reimbursement reductions are material pursuant to Section 1920(a)(30)(A).

Accordingly, Plaintiff's National Association of Chain Drug Stores ("NACDS") and National Community Pharmacists Association ("NCPA"), hereby respond to the Statement of Interest brief filed by the DOJ and request this Court to disregard the Statement of Interest for three reasons: (1) the DOJ *does not* assert that California complied with Section 1920(a)(30)(A) of the Social Security Act, the issue at the crux of Plaintiffs' motion; (2) the DOJ expressly agrees with the Plaintiffs' argument regarding the need for an amended state plan to be approved by CMS where there is a

[1] While 28 USC § 517 permits the DOJ to appear in this Court "to attend to the interests of the United States," this statute does not permit it to file briefing to the detriment and prejudice of other parties. As noted by the DOJ (albeit incorrectly) on November 2, 2009, Plaintiffs filed the instant preliminary injunction motion. The DOJ had ample opportunity to timely respond to Plaintiff's motion, instead it waited until after regular business hours, and one and a half days before the hearing on this matter, to email a copy of its statement to Plaintiffs on Saturday, December 6, 2009. By filing the statement, Plaintiffs have been denied the opportunity to adequately and fully respond to the DOJ arguments so as to protect Plaintiffs interests in this proceeding. While it is true that further argument may be had during the December 7, 2009 hearing, the Court has likely already considered the DOJ's untimely statement, causing prejudice by not allowing Plaintiff's to submit a timely written rebuttal argument prior to the hearing. Therefore, in the interest of justice and fairness, the Court should disregard and refuse to consider the entirety of the DOJ's untimely brief.

material change in the policy or state's operation of the Medicaid Program; and, 3) the DOJ's failure to analyze whether the changes in the reimbursement reductions are changes in policy or are "material" changes implies that it too appreciates that here, Section 1920(a)(30)(A), requires an amendment to the state plan.

II. ARGUMENT

A. THE DOJ *DOES NOT* ASSERT THAT CALIFORNIA COMPLIED WITH SECTION 1920(A)(30)(A) OF THE SOCIAL SECURITY ACT

Plaintiffs' motion for preliminary injunction turns on the issue of whether California failed to comply with Section 1920(a)(30)(A) of the Social Security Act. To comply with 30(A), among other things, reimbursement must be sufficient to ensure "quality of care" and "access" to "enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographical area." 42 USC § 1396(a)(30)(A). Compliance with Section 30(A) requires that the State, when setting reimbursement, "rely on reasonable cost studies, its own or others, that provide reliable data as a basis for its rate setting." *See Plaintiffs Motion*, pp. 9-10; *see also Orthopaedic Hosp.*, 103 F.3d 1491,1499 (9th Cir. 1997). Payments must be related to the cost of providing the services unless there is some justification other than merely budget concerns for not reimbursing providers at that rate. *Id.* In this case, there is no indication that the Department considered any of the 30(A) factors before accepting a more than 4% reduction in Medicaid reimbursement for drug products tied to AWP reimbursement.[2]

Nowhere in the Department of Justice Statement of Interest brief does the DOJ contend that California complied with the requirements under the statute. This is at

[2] Furthermore, the DOJ ignores the fact that California has gone beyond the First Databank settlement regarding the 4% reduction. As asserted in Plaintiffs' moving papers, the California legislature has further reduced reimbursement by the imposition of an "Upper Billing Limit" on drug products in the Medi-Cal program. With this additional reduction, the State was also required to adhere to the factors enumerated under 30(A) and California failed to do so.

the crux of the preliminary injunction motion currently before the court. It is telling that the DOJ claims to be interested in this matter but utterly fails to address this crucial issue.

B. THE DOJ EXPRESSLY AGREES WITH THE PLAINTIFFS' ARGUMENT BUT FAILS TO ANALYZE THE KEY ISSUE

The DOJ expressly agrees with Plaintiffs' argument:

> "The United States has no quarrel with plaintiffs' assertion that all state plan amendments must be approved by CMS or that a state plan must provide that it will be amended whenever 'necessary to reflect' significant changes." [DOJ Brief, p. 10:15 – 17.]

While the DOJ concedes that the state plan must be amended to reflect significant changes, they fail to analyze the key issue of whether the changes in the reimbursement reductions effective September 26, 2009, among others, are "material" and thus necessitate an amendment to the state plan. Rather, the DOJ engages in blame shifting and stating that California was not a party to the *First Databank* settlement; California did not revise its methodology; and California did not make a decision to adopt Section 1920(a)(30)(A). *Id*. at p. 11:3 – 5. The Department of Justice simply misses the point. The DOJ focuses solely on *its* burdens, choosing to ignore the key issue raised by the motion for preliminary injunction – whether the substantial and material changes resulting from the reimbursement reductions will have a severe impact on Medicare and Medi-Cal prescription drug recipients in California.

The Department of Justice contends that "acceptance of the plaintiffs' position would impose impossible administrative burdens on states and the federal government…". Much like the Defendants in this case, the DOJ considers only the "hardships" to its' agency, without considering the Plaintiffs or any non-parties, such as Medi-Cal recipients. As the Ninth Circuit stated "[w]hen balancing 'the medical or financial hardship to [Medi-Cal recipients] against the financial hardship to the state,' that the balance of hardships 'tipped sharply' in favor of the plaintiffs." *See*

Independent Living, 572 F.3d 644, 657-658 (9th Cir. 2009) citing *Beltran v. Meyers*, 677 F.2d 1317, 1322 (9th Cir. 1982).

Moreover, the Ninth Circuit has noted: "In a broader sense, however, the government's interest is the same as the public interest. The government must be concerned not just with the public fisc but also with the public weal. In assessing this broader interest, we are not bound by the government's litigation posture. Rather, we make an independent judgment as to the public interest." *Lopez v. Heckler*, 713 F.2d 1432,1437 (9th Cir. 1983). That is exactly what Plaintiffs ask this Court to do here.

III. CONCLUSION

This Court should disregard the DOJ's Statement of Interest brief in its entirety and grant Plaintiffs' motion for injunctive relief.

Respectfully Submitted:

Dated: December 6, 2009 **DUANE MORRIS LLP**

By: /s/ Yvette D. Roland
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